

Amendment and Response
Applicants: Rudy Mazzocchi et al.
Serial No.: 10/051,492

Attorney Docket: MVA1001USC3

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions and listings of claims in this application.

Listing of Claims:

1 (Currently Amended). A method of performing a balloon angioplasty procedure at a treatment site within a lumen defined by ~~the~~ a wall of a vessel in a patient's vascular system comprising:

providing a filter device including a guidewire and a filter element associated with a distal region of the guidewire, the filter element having a distal end, the filter element being radially self-expandable from a collapsed configuration when the filter element is restrained to an expanded configuration when the filter element is unrestrained;

providing a balloon catheter having an expandable balloon positioned at a distal portion of the balloon catheter;

introducing the guidewire into the lumen of the vessel while the filter element is restrained in the collapsed configuration;

advancing the guidewire through the lumen of the vessel until the filter element is positioned at a desired location distal to the treatment site;

~~removing the restraint~~ removing the restraint on the filter element to cause the filter element to expand to its expanded configuration;

advancing the balloon catheter through the vessel over the guidewire until the balloon is positioned at the treatment site;

expanding the balloon to perform the angioplasty procedure;

capturing emboli released from the treatment site during the angioplasty procedure in the filter element as the emboli ~~flows~~ flow with the patient's blood through the filter element;

removing the balloon catheter from the vessel;

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collapsing the filter element; and
removing the guidewire and filter element from the vessel.

2 (Original). The method of claim 1 wherein the expandable filter element includes a filter mesh.

3 (Currently Amended). The method of claim 1 wherein ~~the~~ restraint on the filter element is removed before the balloon catheter is advanced over the guidewire.

4 (Currently Amended). The method of claim 1 wherein ~~the~~ restraint on the filter element is removed after the balloon catheter is advanced over the guidewire.

5 (Currently Amended). The method of claim 1 wherein ~~the~~ restraint on the filter element is removed before the balloon is expanded.

6 (Currently Amended). The method of claim 4 wherein ~~the~~ restraint on the filter element is removed before the balloon is expanded.

7 (Original). The method of claim 1 wherein in the step of providing a filter device the filter element has a shape in the expanded configuration which defines a cavity having a proximally facing opening.

8 (Original). The method of claim 1 wherein in the step of providing a filter device the filter element is mounted on the distal region of the guidewire.

9 (Original). The method of claim 1 wherein in the step of providing a filter device the guidewire comprises a solid material.

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10 (Original). The method of claim 1 wherein in the step of providing a filter device the guidewire comprises metal.

11 (Original). The method of claim 1 wherein in the step of providing a filter device the guidewire comprises a tapered portion.

12 (Currently Amended). A method of performing a balloon angioplasty procedure at a treatment site within a lumen defined by the wall of a vessel in a patient's vascular system comprising:

- providing a filter device including an guidewire and a filter element mounted on the guidewire, the filter element having a distal end, the filter element being expandable from a collapsed configuration when the filter element is restrained to an expanded configuration when the filter element is unrestrained, the filter element having a shape in the expanded configuration which defines a cavity having a proximally facing opening;

- providing a balloon catheter having an expandable balloon positioned at a distal portion of the balloon catheter;

- introducing the guidewire into the lumen of the vessel while the filter element is restrained in the collapsed configuration;

- advancing the guidewire through the lumen of the vessel until the filter element is positioned at a desired location distal to the treatment site;

- removing the restraint on the filter element to cause the filter element to expand to its expanded configuration;

- advancing the balloon catheter through the vessel over the guidewire until the balloon is positioned at the treatment site;

- expanding the balloon to perform the angioplasty procedure;

- capturing emboli released from the treatment site during the angioplasty procedure in the cavity of the filter element as the emboli flows flow with the patient's blood through the opening in the filter element;

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removing the balloon catheter from the vessel;
closing the opening to the cavity of the filter element; and
removing the guidewire and filter element from the vessel.

13 (Original). The method of claim 12 wherein the expandable filter element includes a filter mesh.

14 (Currently Amended). The method of claim 12 wherein ~~the~~ restraint on the filter element is removed before the balloon catheter is advanced over the guidewire.

15 (Original). The method of claim 12 wherein the step of closing the opening to the cavity is performed before the step of removing the balloon catheter.

16 (Original). The method of claim 12 wherein the step of closing the opening to the cavity of the filter element is performed by withdrawing the filter element proximally toward the balloon catheter.

17 (Currently Amended). The method of claim 12 wherein ~~the~~ restraint on the filter element is removed after the balloon catheter is advanced over the guidewire.

18 (Currently Amended). The method of claim 12 wherein ~~the~~ restraint on the filter element is removed before the balloon is expanded.

19 (Currently Amended). The method of claim 15 wherein ~~the~~ restraint on the filter element is removed before the balloon is expanded.

20 (Original). The method of claim 12 wherein in the step of providing a filter device the guidewire comprises a solid material.

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21 (Original). The method of claim 12 wherein in the step of providing a filter device the guidewire comprises metal.

22 (Original). The method of claim 12 wherein in the step of providing a filter device the guidewire comprises a tapered portion.

23 (Currently Amended). A method of performing a balloon angioplasty procedure at a treatment site within a lumen defined by the wall of a vessel in a patient's vascular system comprising:

providing a filter device including a guidewire and a self-expanding filter element mounted on the guidewire, the filter element having a distal end, the filter element being expandable from a collapsed configuration when the filter element is restrained to an expanded configuration when the filter element is unrestrained, the filter element having a shape in the expanded configuration which defines a cavity having a proximally facing opening, the guidewire extending to at least the distal end of the filter element;

providing a balloon catheter having an expandable balloon positioned at a distal portion of the balloon catheter;

introducing the guidewire into the lumen of the vessel while the filter element is restrained in the collapsed configuration;

advancing the guidewire through the lumen of the vessel until the filter element is positioned at a desired location distal to the treatment site;

removing the restraint on the filter element to cause the filter element to expand to its expanded configuration;

advancing the balloon catheter through the vessel over the guidewire until the balloon is positioned at the treatment site;

expanding the balloon to perform the angioplasty procedure;

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capturing emboli released from the treatment site during the angioplasty procedure in the cavity of the filter element as the emboli ~~flows~~ flow with the patient's blood through the opening in the filter element;
removing the balloon catheter from the vessel;
closing the opening to the cavity of the filter element; and
removing the guidewire and filter element from the vessel.

24 (Original). The method of claim 23 wherein the expandable filter element includes a filter mesh.

25 (Currently Amended). The method of claim 23 wherein ~~the~~ restraint on the filter element is removed before the balloon catheter is advanced over the guidewire.

26 (Original). The method of claim 23 wherein the step of closing the opening to the cavity of the filter element is performed before the step of removing the balloon catheter.

27 (Original). The method of claim 23 wherein the step of closing the opening to the cavity of the filter element is performed by withdrawing the filter element proximally towards the balloon catheter.

28 (Currently Amended). The method of claim 23 wherein ~~the~~ restraint on the filter element is removed after the balloon catheter is advanced over the guidewire.

29 (Currently Amended). The method of claim 23 wherein ~~the~~ restraint on the filter element is removed before the balloon is expanded.

30 (Currently Amended). The method of claim 28 wherein ~~the~~ restraint on the filter element is removed before the balloon is expanded.

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31 (Withdrawn). A system for performing an intravascular procedure at a treatment site within a lumen defined by the wall of a vessel in a patient's vascular system comprising:

a guidewire;

a filter element associated with a distal region of the guidewire, the filter element having a distal end and being expandable from a collapsed configuration when the filter element is restrained to an expanded configuration when the filter element is unrestrained; and

a balloon catheter suitable for performing an angioplasty procedure, the balloon catheter having a lumen sized to slidably accommodate the guidewire, wherein during use the guidewire is positioned across a region of stenosis within the vessel, the filter is expanded, the balloon is expanded within the region of stenosis and wherein embolic material is generated and captured by the filter element before the expandable filter is removed from the vessel.

32 (Withdrawn). The system of claim 31 wherein the filter element is self-expanding.

33 (Withdrawn). The system of claim 31 wherein the filter element comprises nitinol.

34 (Withdrawn). The system of claim 31 wherein the filter element has a shape in the expanded configuration which defines a cavity having a proximally facing opening.

35 (Withdrawn). The system of claim 31 wherein the filter element is mounted on the distal region of the guidewire.

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36 (Withdrawn). The system of claim 31 wherein the guidewire comprises a solid material.

37 (Withdrawn). The system of claim 31 wherein the guidewire comprises metal.

38 (Withdrawn). The system of claim 31 wherein the guidewire comprises a tapered portion.

39 (Withdrawn). A system for performing an intravascular procedure at a treatment site within a lumen defined by the wall of a vessel in a patient's vascular system comprising:

a guidewire;

a filter element mounted on the guidewire, the filter element having a distal end and being expandable from a collapsed configuration when the filter element is restrained to an expanded configuration when the filter element is unrestrained, the filter element having a shape in the expanded configuration which defines a cavity having a proximally facing opening; and

a balloon catheter suitable for performing an angioplasty procedure, the balloon catheter having a lumen sized to slidably accommodate the guidewire, wherein during use the guidewire is positioned across a region of stenosis within the vessel, the filter is expanded, the balloon is expanded within the region of stenosis and wherein embolic material is generated and captured by the filter element before the expandable filter is removed from the vessel.

40 (Withdrawn). The system of claim 39 wherein the filter element is self-expanding.

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41 (Withdrawn). The system of claim 39 wherein the filter element comprises nitinol.

42 (Withdrawn). The system of claim 39 wherein the guidewire comprises a solid material.

43 (Withdrawn). The system of claim 39 wherein the guidewire comprises metal.

44 (Withdrawn). The system of claim 39 wherein the guidewire comprises a tapered portion.

45 (Withdrawn). A system for performing an intravascular procedure at a treatment site within a lumen defined by the wall of a vessel in a patient's vascular system comprising:

a guidewire;

a self-expandable filter element mounted on the guidewire, the filter element having a distal end and being expandable from a collapsed configuration when the filter element is restrained to an expanded configuration when the filter element is unrestrained, the filter element having a shape in the expanded configuration which defines a cavity having a proximally facing opening, the guidewire extending through the cavity to at least the distal end of the filter element; and

a balloon catheter suitable for performing an angioplasty procedure, the balloon catheter having a lumen sized to slidably accommodate the guidewire, wherein during use the guidewire is positioned across a region of stenosis within the vessel, the filter is expanded, the balloon is expanded within the region of stenosis and wherein embolic material is generated and captured by the filter element before the expandable filter is removed from the vessel.

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- 46 (Withdrawn). The system of claim 45 wherein the filter element comprises nitinol.
- 47 (Withdrawn). The system of claim 45 wherein the guidewire comprises a solid material.
- 48 (Withdrawn). The system of claim 45 wherein the guidewire comprises metal.
- 49 (Withdrawn). The system of claim 45 wherein the guidewire comprises a tapered portion.
- 50 (Currently Amended). A method of performing a balloon angioplasty procedure at a treatment site within a lumen defined by the wall of a vessel in a patient's vascular system comprising:
- providing a filter device including a filter element and means for carrying the filter element, the filter element having a distal end, the filter element being expandable from a collapsed configuration when the filter element is restrained to an expanded configuration when the filter element is unrestrained;
 - providing a balloon catheter having an expandable balloon positioned at a distal portion of the balloon catheter;
 - introducing the carrying means into the lumen of the vessel while the filter element is restrained in the collapsed configuration;
 - advancing the carrying means through the lumen of the vessel until the filter element is positioned at a desired location distal to the treatment site;
 - removing the restraint on the filter element to cause the filter element to expand to its expanded configuration;

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- advancing the balloon catheter through the vessel over the carrying means until the balloon is positioned at the treatment site;
- expanding the balloon to perform the angioplasty procedure;
- capturing emboli released from the treatment site during the angioplasty procedure in the filter element as the emboli flows flow with the patient's blood through the filter element;
- removing the balloon catheter from the vessel;
- collapsing the filter element; and
- removing the carrying means and filter element from the vessel.

51 (Currently Amended). A method of performing a balloon angioplasty procedure at a treatment site within a lumen defined by the wall of a vessel in a patient's vascular system comprising:

- providing a filter device including a filter element and means for carrying the filter element, the filter element having a distal end, the filter element being expandable from a collapsed configuration when the filter element is restrained to an expanded configuration when the filter element is unrestrained, the filter element having a shape in the expanded configuration which defines a cavity having a proximally facing opening;

- providing a balloon catheter having an expandable balloon positioned at a distal portion of the balloon catheter;

- introducing the carrying means into the lumen of the vessel while the filter element is restrained in the collapsed configuration;

- advancing the carrying means through the lumen of the vessel until the filter element is positioned at a desired location distal to the treatment site;

- removing the restraint on the filter element to cause the filter element to expand to its expanded configuration;

- advancing the balloon catheter through the vessel over the carrying means until the balloon is positioned at the treatment site;

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expanding the balloon to perform the angioplasty procedure;
capturing emboli released from the treatment site during the angioplasty procedure in the cavity of the filter element as the emboli ~~flows~~ flow with the patient's blood through the opening in the filter element;
removing the balloon catheter from the vessel;
closing the opening to the cavity of the filter element; and
removing the carrying means and filter element from the vessel.

52 (Currently Amended). A method of performing a balloon angioplasty procedure at a treatment site within a lumen defined by the wall of a vessel in a patient's vascular system comprising:

providing a filter device including a radially self-expanding filter element and means for carrying the filter element, the filter element having a distal end, the filter element being expandable from a collapsed configuration when the filter element is restrained to an expanded configuration when the filter element is unrestrained, the filter element having a shape in the expanded configuration which defines a cavity having a proximally facing opening, the carrying means extending to at least the distal end of the filter element;

providing a balloon catheter having an expandable balloon positioned at a distal portion of the balloon catheter;

introducing the carrying means into the lumen of the vessel while the filter element is restrained in the collapsed configuration;

advancing the carrying means through the lumen of the vessel until the filter element is positioned at a desired location distal to the treatment site;

removing ~~the~~ restraint on the filter element to cause the filter element to expand to its expanded configuration;

advancing the balloon catheter through the vessel over the carrying means until the balloon is positioned at the treatment site;

expanding the balloon to perform the angioplasty procedure;

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capturing emboli released from the treatment site during the angioplasty procedure in the cavity of the filter element as the emboli flows flow with the patient's blood through the opening in the filter element;
removing the balloon catheter from the vessel;
closing the opening to the cavity of the filter element; and
removing the carrying means and filter element from the vessel.

53 (Withdrawn). A system for performing an intravascular procedure at a treatment site within a lumen defined by the wall of a vessel in a patient's vascular system comprising:

a filter element having a distal end and being expandable from a collapsed configuration when the filter element is restrained to an expanded configuration when the filter element is unrestrained;

means for carrying the filter element; and

a balloon catheter suitable for performing an angioplasty procedure, the balloon catheter having a lumen sized to slidably accommodate the carrying means, wherein during use the carrying means is positioned across a region of stenosis within the vessel, the filter is expanded, the balloon is expanded within the region of stenosis and wherein embolic material is generated and captured by the filter element before the expandable filter is removed from the vessel.

54 (Withdrawn). A system for performing an intravascular procedure at a treatment site within a lumen defined by the wall of a vessel in a patient's vascular system comprising:

a filter element having a distal end and being expandable from a collapsed configuration when the filter element is restrained to an expanded configuration when the filter element is unrestrained, the filter element having a shape in the expanded configuration which defines a cavity having a proximally facing opening;

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means for carrying the filter element; and
a balloon catheter suitable for performing an angioplasty procedure, the balloon catheter having a lumen sized to slidably accommodate the carrying means, wherein during use the carrying means is positioned across a region of stenosis within the vessel, the filter is expanded, the balloon is expanded within the region of stenosis and wherein embolic material is generated and captured by the filter element before the expandable filter is removed from the vessel.

55 (Withdrawn). A system for performing an intravascular procedure at a treatment site within a lumen defined by the wall of a vessel in a patient's vascular system comprising:

a self-expandable filter element having a distal end and being expandable from a collapsed configuration when the filter element is restrained to an expanded configuration when the filter element is unrestrained, the filter element having a shape in the expanded configuration which defines a cavity having a proximally facing opening;

means for carrying the filter element, the carrying means extending extending through the cavity to at least the distal end of the filter element; and

a balloon catheter suitable for performing an angioplasty procedure, the balloon catheter having a lumen sized to slidably accommodate the carrying means, wherein during use the carrying means is positioned across a region of stenosis within the vessel, the filter is expanded, the balloon is expanded within the region of stenosis and wherein embolic material is generated and captured by the filter element before the expandable filter is removed from the vessel.

56 (Withdrawn). A system for filtering emboli from blood flowing through a lumen defined by the wall of a vessel comprising:

a guidewire;

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a filter element carried by the guidewire, the filter element having a distal end, the filter element being expandable from a collapsed delivery configuration to an expanded deployed configuration when the filter element is deployed in the lumen of the vessel, the filter element being collapsible from the expanded deployed configuration to a retrieval configuration for removal from the vessel, the filter element having a shape in the expanded configuration which defines a cavity having a proximally facing opening configured to filter emboli from blood when deployed in the vessel; and

a balloon catheter having a lumen extending therethrough and having a distal portion, the balloon catheter sized to be accommodated within the lumen of the vessel, the lumen of the balloon catheter sized to accommodate the guidewire and the filter element in its delivery configuration, the distal portion of the balloon catheter being configured to accommodate the filter element in its retrieval configuration during removal of the balloon catheter and filter element from the vessel.

57 (Withdrawn). A system for filtering emboli from blood flowing through a lumen defined by the wall of a vessel comprising:

a filter element having a distal end, the filter element being expandable from a collapsed delivery configuration to an expanded deployed configuration when the filter element is deployed in the lumen of the vessel, the filter element being collapsible from the expanded deployed configuration to a retrieval configuration for removal from the vessel, the filter element having a shape in the expanded configuration which defines a cavity having a proximally facing opening configured to filter emboli from blood when deployed in the vessel;

means for carrying the filter element;

a balloon catheter defining a lumen extending therethrough and having a distal portion, the balloon catheter sized to be accommodated within the lumen of the vessel, the lumen of the balloon catheter sized to accommodate the carrying

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means and the filter element in its delivery configuration, the distal portion of the balloon catheter being configured to accommodate the filter element in its retrieval configuration during removal of the balloon catheter and filter element from the vessel.

58 (Currently Amended). A method of protecting a patient from embolism during a balloon angioplasty procedure at a site of stenosis within a lumen defined by the wall of a vessel in a patient's vascular system comprising:

providing a filter device including a guidewire and a filter element mounted on the guidewire, the filter element having a distal end, the filter element being expandable from a collapsed delivery configuration to an expanded deployed configuration when the filter element is deployed in the lumen of the vessel, the filter element being collapsible from the expanded deployed configuration to a retrieval configuration for removal from the vessel, the filter element having a shape in the expanded configuration which defines a cavity having a proximally facing opening configured to filter emboli from blood when deployed in the vessel;

providing a balloon catheter having a lumen extending therethrough and having a distal portion, the balloon catheter sized to be accommodated within the vessel, the lumen of the balloon catheter sized to accommodate the guidewire, the distal portion of the balloon catheter being configured to accommodate the filter element in its retrieval configuration during removal of the balloon catheter and filter element from the vessel;

introducing the balloon catheter into the lumen of the vessel;

advancing the guidewire through the lumen of the ~~delivery~~ balloon catheter until the filter element is positioned at a desired location distal to the site of stenosis;

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deploying the filter element to its expanded configuration prior to performing the balloon angioplasty procedure;
performing the balloon angioplasty procedure at the site of stenosis;
collapsing the filter element to its retrieval configuration after completion of the intravascular procedure;
accommodating the filter element in its retrieval configuration at the distal portion of the balloon catheter; and
removing the balloon catheter and filter element from the vessel.

59 (Currently Amended). A method of protecting a patient from embolism during a balloon angioplasty procedure at a site of stenosis within a lumen defined by the wall of a vessel in a patient's vascular system comprising:

providing a filter device including a filter element and means for carrying the filter element, the filter element having a distal end, the filter element being expandable from a collapsed delivery configuration to an expanded deployed configuration when the filter element is deployed in the lumen of the vessel, the filter element being collapsible from the expanded deployed configuration to a retrieval configuration for removal from the vessel, the filter element having a shape in the expanded configuration which defines a cavity having a proximally facing opening configured to filter emboli from blood when deployed in the vessel;

providing a balloon catheter having a lumen extending therethrough and having a distal portion, the balloon catheter sized to be accommodated within the vessel, the lumen of the balloon catheter sized to accommodate the carrying means, the distal portion of the balloon catheter being configured to accommodate the filter element in its retrieval configuration during removal of the balloon catheter and filter element from the vessel;

introducing the balloon catheter into the lumen of the vessel;

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advancing the carrying means through the lumen of the delivery balloon catheter until the filter element is positioned at a desired location distal to the site of stenosis;

deploying the filter element to its expanded configuration prior to performing the balloon angioplasty procedure;

performing the balloon angioplasty procedure at the site of stenosis;

collapsing the filter element to its retrieval configuration after completion of the intravascular procedure;

accommodating the filter element in its retrieval configuration at the distal portion of the balloon catheter; and

removing the balloon catheter and filter element from the vessel.

60 (Withdrawn). A system for filtering emboli from blood flowing through a lumen defined by the wall of a vessel comprising:

a balloon catheter having a lumen;

a guidewire sized to be accommodated within the lumen of the balloon catheter; and

a filter element carried by the guidewire, the shape of the filter element being transformable from a delivery configuration to an expanded deployed configuration to a collapsed retrieval configuration, the filter element being sized to be delivered through the lumen of the balloon catheter in its delivery configuration to a desired site within the vessel, to filter emboli within the vessel in its expanded deployed configuration and to be removed in its retrieval configuration from the vessel by the balloon catheter.

61 (Withdrawn). A system for filtering emboli from blood flowing through a lumen defined by the wall of a vessel comprising:

a balloon catheter having a lumen; and

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a filter device including a filter element and a means for carrying the filter element, the shape of the filter element being transformable from a delivery configuration to an expanded deployed configuration to a collapsed retrieval configuration, the filter element being sized to be delivered through the lumen of the balloon catheter in its delivery configuration to a desired site within the vessel, to filter emboli within the vessel in its expanded deployed configuration and to be removed in its retrieval configuration from the vessel by the balloon catheter.

62 (Withdrawn). A system for filtering emboli at a desired site from blood flowing through a lumen defined by the wall of a vessel comprising:

- a guidewire;
- a filter carried by the guidewire, the filter being expandable from a delivery configuration to a deployed configuration and being collapsible from the deployed configuration to a retrieval configuration; and
- a balloon catheter having a lumen configured for delivery of the filter carried by the guidewire in the delivery configuration to the desired site in the vessel, and having a distal portion configured for retrieval of the filter carried by the guidewire from the vessel in the retrieval configuration.

63 (Withdrawn). A system for filtering emboli at a desired site from blood flowing through a lumen defined by the wall of a vessel comprising:

- a filter device including a filter element and means for carrying the filter element, the filter element being expandable from a delivery configuration to a deployed configuration and being collapsible from the deployed configuration to a retrieval configuration; and
- a balloon catheter having a lumen configured for delivery of the filter element carried by the carrying means in the delivery configuration to the desired site in the vessel, and having a distal portion configured for retrieval of the filter carried by the carrying means from the vessel in the retrieval configuration.